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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
[illegible]	[illegible]/99	ADAMCZEWSKI	MD-5176/LEA3

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EXAMINER	
SCHNIZER, R	

ART UNIT	PAPER NUMBER
1632	25

DATE MAILED: 08/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/303,232	Applicant(s) ADAMCZEWSKI ET AL.	
	Examiner Richard Schnizer	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,10 and 22-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10 and 22-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Prosecution Application

The request filed on 6/4/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/303,232 is acceptable and a CPA has been established. An action on the CPA follows.

A preliminary amendment was received and entered as Paper No. 24 on 6/4/01. Claims 8, 9,11-20, 32, and 33 were canceled as requested. Claims 1-7, 10 and 22-31 remain pending and are under consideration in this Office Action.

The Declaration of Dr. Adamczewski was received and entered as Paper No. 21 on 6/4/01. The Declaration has been fully considered, and is sufficient to overcome the rejection of claims 1-7, 10, and 22-31 for lack of enablement, as set forth in Paper No. 13. However, new grounds of rejection under 35 USC 112, first paragraph are set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

Claims 1-10 and 22-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to three distinct genuses of nucleic acids that encode a complete or partial insect acetylcholine receptor subunit having the ability to form homooligomeric acetylcholine receptors when expressed in host cells. In embodiment (b) of the claims, the three genuses encompass nucleic acids which hybridize to sequences from SEQ ID NOS: 1, 3, or 5 under specific conditions. A sequence search performed by the PTO indicates that the nucleotide sequences of SEQ ID NOS: 1, 3, and 5 display substantial variability with respect to each other. SEQ ID NO:1 is about 22% identical to SEQ ID NO:3, and about 27% identical to SEQ ID NO: 5, whereas SEQ ID NOS: 3 and 5 are about 38% identical to each other. See enclosed sequence alignments. These sequences would not hybridize to each other under the conditions set forth in the claims, thus the claims are drawn to three distinct and non-overlapping genuses of nucleic acids. The issue under consideration in this rejection is whether the specification has adequately described each of these genuses.

The following analysis is based on the Guidelines on Written Description published at FR 66(4) 1099-1111 (January 5, 2001) (also available at www.uspto.gov). The following passage on the treatment of genus claims is particularly relevant.

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to

drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Because the specification discloses only a single species of each claimed genus, it must be determined whether each species is representative of its genus. The specification discloses no relevant identifying characteristics of the other members of any claimed genus, nor any functional characteristic coupled with a correlation between structure and function. For example, although SEQ ID NOS:1, 3, and 5 all share a common activity, neither the specification nor the prior art teaches any specific correlation between any physical structure of the nucleic acid and the ability of the encoded product to form a complete or partial homooligomeric insect acetylcholine receptor. Thus it is unknown what common structural features allow a nucleic acid to encode a protein with the function of a homooligomeric acetylcholine receptor, although it is apparent that substantial structural variation may occur within the broad genus of nucleic acids encoding insect acetylcholine receptors as indicated by the low degree of sequence identity between SEQ ID NOS: 1, 3, and 5. One might argue that the encoded proteins show a reasonable degree of amino acid sequence similarity, however in the absence of any disclosure of what particular sequences are required for function, there can be no disclosure of any structure/function correlation which provides an adequate written description of any of the claimed genuses.

This portion of the rejection may be overcome by deleting embodiment (b) from the claims, i.e. by limiting the claims to nucleic acids which encode the polypeptides encoded by the sequences of embodiment (a), and to the complements of those nucleic acids.

Absent any description of relevant identifying characteristics or the disclosure of any correlation between the structure and function which is common to the species of the claimed genuses, one of skill in the art could not conclude that Applicant was in possession of the claimed genuses at the time of filing, based on the disclosure of only a single species from each genus.

Furthermore, the specification fails to provide an adequate written description of what distinguishes an "insect" homooligomeric acetylcholine receptor from a non-insect homooligomeric acetylcholine receptor. This conclusion is based on two facts. First, SEQ ID NOS:1, 3, and 5, display a high degree of variability with respect to each other, as noted above. For example, SEQ ID NO:1 is about 22% identical to SEQ ID NO:3, and about 27% identical to SEQ ID NO: 5, whereas SEQ ID NOS: 3 and 5 are about 38% identical to each other. Second, a search of the prior art reveals mammalian homologues of these sequences which encode alpha 7 acetylcholine receptor subunits, and which have a similar level of identity with the claimed sequences. For example, a nucleic acid encoding a mouse alpha 7 acetylcholine receptor subunit is about 28% identical to SEQ ID NO:3, whereas SEQ ID NO:1 is only 22% identical to SEQ ID NO:3. Further, a nucleic acid encoding a human alpha 7 acetylcholine receptor subunit is about 25% identical to SEQ ID NO:5, compared to the 27% identity between SEQ ID NOS: 1 and 5. See enclosed sequence alignments. The specification discloses no relevant identifying

characteristics or structure /function relationships which one of skill in the art, in the absence of any information concerning the source of the nucleic acids, could use to distinguish the mammalian sequences from the insect sequences. For this reason, one of skill in the art could not conclude that applicant was in possession of the genus of nucleic acids encoding "insect" homooloigomeric acetylcholine receptors at the time of filing.

This portion of the rejection may be overcome by deleting the word "insect" from the claims.

Enablement

Claims 1-10 and 22-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids which encode the polypeptides of SEQ ID NOS: 2, 4 and 6, does not reasonably provide enablement for a nucleic acids encoding an insect homooloigomeric acetylcholine receptor as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claimed invention is a nucleic acid encoding a complete or partial insect acetylcholine receptor subunit having the ability to form homooligomeric acetylcholine receptors when expressed in host cells. The issue under consideration in this rejection is whether or not the specification teaches how to determine what constitutes an insect acetylcholine receptor subunit as opposed to a non-insect acetylcholine receptor subunit. Clearly, one of skill in the art could

identify a protein as either insect or non-insect based upon the source of the given protein. But, if that source is unknown, could one identify the protein as insect or non-insect based solely in the sequence of the protein and the teachings of the specification and the prior art? As discussed above, under written description, SEQ ID NO:1 is about 22% identical to SEQ ID NO:3, and about 27% identical to SEQ ID NO: 5, whereas SEQ ID NOS: 3 and 5 are about 38% identical to each other. A search of the prior art reveals mammalian homologues of these sequences which encode alpha 7 acetylcholine receptor subunits, and which have a similar level of identity with the claimed sequences. For example, a nucleic acid encoding a mouse alpha 7 acetylcholine receptor subunit is about 28% identical to SEQ ID NO:3, whereas SEQ ID NO:1 is only 22% identical to SEQ ID NO:3. Further, a nucleic acid encoding a human alpha 7 acetylcholine receptor subunit is about 25% identical to SEQ ID NO:5, compared to the 27% identity between SEQ ID NOS: 1 and 5. See enclosed sequence alignments. Neither the specification nor the prior art provides guidance as to how to distinguish insect from non-insect sequences based solely on the sequence information. No characteristics which are unique to insect sequences are disclosed in the specification or taught in the prior art. Thus, one of skill in the art would have to perform undue experimentation to make the nucleic acids encoding insect acetylcholine receptor subunits, other than those encoding SEQ ID NOS: 2, 4, and 6, except by isolation of the nucleic acids from an insect source. For this reason, one of skill in the art could not practice the invention commensurate in scope with the claims.

This rejection may be overcome by deleting the word "insect" from the claims. In the event that this rejection is overcome, the following rejection will still apply to claim 10.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of preparing a polypeptide encoded by a nucleic acid of claim 1 wherein the nucleic acid is operably linked to an expression control sequence, does not reasonably provide enablement for expression of polypeptides encoded by a nucleic acid of claim 1 wherein the nucleic acid is not operably linked to an expression control. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The invention is a method for expressing polypeptides encoded by nucleic acids of claim 1. The claims encompass nucleic acids operably linked to an expression control sequence, and nucleic acids which are not linked to an expression control sequence. It is well known to those skilled in the art that expression of DNA sequences requires transcription by RNA polymerase, which is in turn dependent on productive binding of the polymerase to an expression control sequence. In the absence of such a sequence, a skilled artisan would have to perform undue experimentation in order to use the invention. This rejection may be overcome by amending claim 10 to require operable linkage to a transcription control sequence, such as is recited in claim 3.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 103-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is usually in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Patsy Zimmerman whose telephone number is 703-308-8338.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~/630

Richard Schnizer, Ph.D.